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Amdt. dated: November 30, 2005

Response to Office Action of September 8, 2005

Amendments to the Claims:

Listing of the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (currently amended) A method for characterizing a test subject's risk of developing or

having cardiovascular disease, comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or

both in a bodily sample from the test subject, said bodily sample being blood, serum, plasma,

circulating leukocytes or blood cells-any combination thereof,

wherein elevated levels of MPO activity or MPO mass or both in the bodily sample

blood, serum, plasma or blood cells of the test subject as compared to at least one predetermined

value based on levels of MPO activity, MPO mass or both, respectively, in comparable bodily

samples obtained from a population of control subjects indicates that the test subject is at risk of

developing or having cardiovascular disease.

2. (withdrawn/amended) The method of claim 1 wherein the level of myeloperoxidase

activity in one or more populations of circulating leukocytes in the test subject's bodily-sample

blood is determined by an assay which employs a peroxidase substrate and flow cytometry.

3. (withdrawn) The method of claim 1, wherein said predetermined value is a single

normalized value or a range of normalized values and is based on the MPO activity levels in

comparable bodily samples from the general population or a select population of subjects.

4. (withdrawn) The method of claim 1 wherein said predetermined value is a single

representative value or a range of representative values and is based on the MPO activity levels

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in comparable bodily samples from the general population or a select population of control subjects.

- 5. (withdrawn) The method of claim 1, wherein said predetermined value is a plurality of predetermined MPO activity level ranges that are based on the MPO activity levels in comparable bodily samples from the general population or a select population of control subjects.
- 6. (withdrawn/amended) The method of claim 1, wherein the bodily sample blood-cells comprises circulating leukocytes selected from the group consisting of leukocytes, neutrophils, monocytes, mononuclear lymphocytes, sub-populations of neutrophils, sub-populations of monocytes, and sub-populations of mononuclear lymphocytes, or any combination thereof.
- 7. (previously presented) The method of claim 1, wherein the levels of myeloperoxidase mass in the test subject's bodily sample is determined by an immunological technique.
- 8. (previously presented) The method of claim 1, wherein said predetermined values is a single normalized value or a range of normalized values and is based upon the MPO mass levels in comparable bodily samples from the general population or a select population of control subjects.

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9. (previously presented) The method of claim 1, wherein said predetermined value is a single representative value or a range of representative values and is based upon the MPO mass levels in comparable bodily samples from the general population or a select population of control subjects.

10. (previously presented) The method of claim 1, wherein said predetermined value is a plurality of predetermined MPO mass level ranges which are based on the MPO mass levels in comparable bodily samples from the general population or a select population of control subjects.

11-22 canceled

23. (currently amended) A method of assessing a test subject's risk of developing or having cardiovascular disease, comprising

comparing levels of myeloperoxidase in blood, serum, plasma, <u>circulating leukocytes</u>, or <u>blood_cells_any_combination_thereof</u> from the test subject with levels of myeloperoxidase in blood, serum, plasma, <u>circulating leukocytes</u> or <u>blood_cells_any_combination_thereof_from_a_population_of_control_subjects;</u> and

wherein the difference between the levels of myeloperoxidase in blood, serum, plasma, circulating leukocytes, or blood cells any combination thereof from the test subject and the levels of myeloperoxidase in blood, serum, plasma, circulating leukocytes or blood cells any combination thereof from the population of control subjects is indicative of the extent of the test subject's risk of developing or having cardiovascular disease.

- 24. canceled.
- 25. (previously presented) The method of claim 1, wherein the test subject is a non-

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diabetic, non-hypertensive, non-smoker.

26. (currently amended) A method of assessing a test subject's risk of experiencing an acute adverse cardiovascular event, comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in blood, serum, plasma, circulating leukocytes or blood-cells any combination thereof from the test subject;

wherein elevated levels of MPO activity or MPO mass or both in blood, serum, plasma, circulating leukocytes or blood cells or any combination thereof of the test subject as compared to levels of MPO activity, MPO mass, or both, respectively in blood, serum, plasma, circulating leukocytes or blood cells any combination thereof obtained from control subjects indicates that the test subject is at risk of experiencing an acute adverse cardiovascular event.

27. (currently amended) A method of determining a test subject's risk of requiring medical intervention, comprising:

determining levels of a risk predictor in a bodily sample from the test subject, wherein said risk predictor is myeloperoxidase activity, myeloperoxidase mass, or any combination thereof, and wherein said bodily sample is blood, serum, plasma, circulating leukocytes or -blood eells any combination thereof;

comparing levels of said risk predictor in the bodily sample of the test subject to levels of said risk predictor in comparable samples obtained from a control population,

wherein a patient whose levels of said risk predictor is characterized as being elevated in comparison to levels of said risk predictor in a comparable bodily sample obtained from individuals in a control population is at risk of requiring medical intervention.

28. (currently amended) The method of claim 23, wherein the level of myeloperoxidase in the one or more populations of circulating leukocytes in the test subject's bodily sample blood is determined by an assay which involves exposing the circulating

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<u>leukocytes to a peroxidase substrate and subjecting the substrate exposed circulating leukocytes</u>
<u>to flow cytometry; and</u>

wherein the level of myeloperoxidase in the test subject's one or more populations of circulating leukocytes is correlated with one or more flow cytometry parameters.

- 29. (previously presented) The method of claim 26, wherein the test subject's risk of experiencing an acute cardiovascular event is determined by comparing levels of myleperoxidase mass in the test subject's bodily sample to levels of myeloperoxidase mass in comparable samples obtained from a control population.
- 30. (previously presented) The method of claim 27, wherein the test subject's risk of requiring medical intervention is determined by comparing levels of myleperoxidase mass in the test subject's bodily sample to levels of myeloperoxidase mass in comparable samples obtained from a control population.
- 31. (currently amended) The method of claim-1 A method for characterizing a test subject's risk of having cardiovascular disease, comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the test subject, wherein the bodily sample is blood, serum, or plasma, and

wherein elevated levels of MPO activity or MPO mass or both in the subject's bodily sample as compared to levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from a population of control subjects indicates that the test subject is at risk of having cardiovascular disease.

32. (new) The method of claim 23 wherein the level of myeloperoxidase in one or more populations of the test subject's circulating leukocytes is determined by an assay which employs an antibody that binds to myeloperoxidase and flow cytometry.

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33. (new) A method of characterizing a test subject's risk of having cardiovascular disease comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the test subject, said bodily sample being blood, serum, plasma, circulating leukocytes or any combination thereof;

wherein a test subject whose bodily sample contains levels of MPO activity or MPO mass or both that are higher than a control value based on levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from a population of control subjects is at greater risk of having cardiovascular disease than a test subject whose bodily sample contains levels of MPO activity or MPO mass or both that are equal to or less than the control value.